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From: Striker Striker & Stenby

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Ser. No. 10/587,278

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REMARKS

I. Supporting Disclosure for the Claim Wording Changes

The previously pending main method claim 32 has now been limited to a method of repairing, strengthening, and restructuring <u>hair</u>. The wording regarding "protecting" has been deleted to avoid disclosures in the prior art of record, particularly the sort of "protecting" that merely involves shielding the hair from physical contact with various reactive species that will react with the hair and thus weaken the hair. Also see the first paragraph on page 6 of the applicants' written disclosure in the originally filed specification for supporting wording.

The claimed method thus involves changing the structure of the hair so as to repair or strengthen or restructure the hair. The changed wording in the first three lines of independent method claim 32 is supported by wording in the first line of canceled method claim 18, the first paragraph on page 1 of the applicants' originally filed specification, and the last <u>full</u> (the fourth <u>full</u>) paragraph on page 2 of applicants' specification. The limitation to a method of treating hair is supported by the third <u>full</u> paragraph on page 2 of the applicants' specification.

In addition, applicants have filed comparative experimental results that

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clearly establish the effectiveness of the claimed method according to claim 32 using exemplary agent compositions according to the present invention in increasing the hair strength (tear resistance) or the rubbing resistance (abrasion resistance) of the hair. These results for rubbing resistance appear on pages 8 to 12 of the applicants' specification and are illustrated in figs. 1 to 3 of applicants' specification. Example 4 on page 13 of the applicants' specification also provides comparative experimental results that show that the method according to the invention improves the tear resistance or strength of human hair. The preferred tested compounds on pages 8 to 14 of applicants' originally filed specification include a chloride, an acetate, and a citrate of the compound of formula I.

The experimental results in these experiments are performed using scientific methods. Quantitative properties are measured during the experiments and the methods used are based on reliable established testing procedures. Comparison was made between methods employing the treatment agents according to the invention and comparative methods in which the same composition is applied to the hair, except that the treatment agent of the invention is omitted (a control composition). Statistical analysis shows that significant improvements are obtained in all cases.

Thus the quantitative changes in the measured properties clearly show that changes in the structure of the hair have occurred due to the treatment methods according to claim 32.

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The term "salts of the compound of formula I" and the term "salts of the compounds of formula II" are no longer used in the amended independent claim 32 and the new independent claim 40. These deletions from claim 32 are allowable, because applicants are entitled to limit their subject matter to preferred embodiments. Furthermore some of the wording regarding salts in the original claim 32 was misleading and the terminology regarding "salts" will be explained further herein below with respect to the indefiniteness rejection.

A new dependent claim 39 has been added to cover preferred embodiments of the method of claim 32, which are limited to the preferred chloride, acetate and citrate of the compound of formula I. This dependent claim is supported by page 3, line 3, of the originally filed specification, the comparative experimental results on pages 8 to 13 of the applicants' specification and numerous examples on pages 13 to 21 of the applicants' specification.

In addition, a new independent method claim 40 has been added, which is limited to a method of improving the <u>tear resistance</u> or the <u>abrasion resistance</u> of hair. Otherwise the new claim 40 includes the same features and limitations as the previously pending claim 32, i.e. the effective ingredient is limited to the same compounds as in claim 32. Also the new independent claim 40 is supported by the applicants' general teachings, and particularly by the comparative experimental results in the applicants' specification on pages 8 to 13, which show

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the effectiveness of the method in increasing tear resistance or abrasion resistance for exemplary compounds of formulas I and II.

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New dependent method claim 41 contains the same subject matter as new dependent claim 39, but depends on independent claim 40 instead of independent claim 32.

II. Indefiniteness Rejection

Claims 32 to 38 were rejected as indefinite under 35 U.S.C. 112, 2nd paragraph, for failing to particularly point out and distinctly claim the subject matter of the invention.

Several mistakes were indeed made in drafting the original claim 32. First, formula I only shows a single neutral compound, namely a compound known as trigonelline, among other names (see page 3, lines 8 to 13, of applicants' specification). This neutral compound is known to exist in the form shown by the structural formula I, in which there is a positively charged quaternary nitrogen atom and a negatively charged oxygen atom within a single molecule of the compound. In other words, the neutral compound of formula I is a so-called zwitterionic compound. Zwitterions are also called "inner" salts in some references, because they comprise molecules, each of which include a positively charged site and a negatively charged site separated by several atoms from the

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positively charged site, for example as shown in the structural formula I in claim 32.

For the aforesaid reasons in the amended claim 32 the term "compounds of formula (I)" has been changed to "compound of formula (I)".

Some references in the chemical arts describe the compound of formula

(I) as an "inner" salt, but it should not be confused with a simple salt that is
formed by reaction of two different compounds, namely an acid compound with a
base compound.

The compounds of formula II are referred to as "salts of the compound of formula I" according to the last sentence in the seventh full paragraph on page 3 of the applicants' specification. For example some of them can be formed by reaction of an acid, such as HCI or acetic acid, with the neutral compound of formula I. That is the reason that the term "salts" appears in the applicants' specification.

However it should be apparent that the use of the term "salts" to designate either the compound of formula (I) or the compounds of formula (II) is confusing due to the occasional use of the term "inner salt" for the compound of formula (I). As a result for these considerations the term "salt" was omitted from the claims.

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The scope of the subject matter that the applicants consider to be their DEC 2 1 2010 invention clearly encompasses the single compound of formula 1 and the compounds defined by formula II, with the various anions and cations limited according to claim 32 or 40. The use of the term "salts" to designate one or more of these compounds in the claims is thus unnecessary.

For the aforesaid reasons and because of the changes in the claim wording, withdrawal of the rejection of amended claims 32 to 36 and 38 as indefinite under 35 U.S.C. 112, 2nd paragraph, is respectfully requested.

It is also respectfully submitted that new claims 39 to 41 should not be rejected on the aforesaid grounds for indefiniteness under 35 U.S.C. 112, 2nd paragraph.

III. Specification Changes

Although the written description was not objected to, one paragraph on page 3 appears to contain grammatical and translational error and has been corrected by the above changes. No new matter has been entered because the changes would be obvious to one skilled in the chemical arts.

Entry of the changes in the written description on page 3 is respectfully requested since the changes provide a disclosure that is clearer, logically more correct and easier to understand.

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IV. Obviousness Rejection

Claims 32 to 38 were rejected as obvious under 35 U.S.C. 103 (a) over U.S. Patent 5,133,958 (US '958) and U.S. Patent 6,861,077 (US '077).

A. Applicants' Claimed Method

Applicants' method is a <u>new</u> method of using a known compound and its salts, the known compound being trigonelline (The Office Action indicates that the method as claimed is not anticipated by any single prior art references, which is equivalent to admitting that the claimed method is novel).

The claimed method comprises <u>bringing</u> the trigonelline and/or one of its salts as claimed in claim 32 or 40 into contact with the <u>hair</u> for an acting period of 1 to 60 minutes at a temperature between 10°C and 70°C and then <u>rinsing</u> the active ingredient or ingredients from the hair.

B. Differences between the Claimed Invention and the Prior Art

US '958 discloses a method for hair care, for combating progressive hair loss and for stimulating fresh hair growth of human hair (column 1, lines 4 to 6).

US '958 discloses that the method uses an agent comprising respective

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amounts of trigonelline <u>and</u> vitamin B6 in column 1, lines 27 to 30. The vitamin B6 is a required ingredient according to U.S. '958 (see claims 1, 2 and the other independent claims of US'958). The agent may also include other adjuvant substances including amino acid (column 2).

US '958 teaches that the method for hair care, for combating progressive hair loss and for stimulating fresh hair growth of human hair comprises daily oral administration of their agent comprising trigonelline and vitamin B6 (column 3, lines 16 to 23). In contrast, the applicants' effective ingredient comprising the compound of formula (I) and/or the compounds of formula (II) is(are) brought into contact with the hair for the stated acting period and then after the acting period rinsed from the hair.

On the other hand, US '958 also teaches a method for hair care, for combating progressive hair loss and for stimulating fresh hair growth of human hair comprising applying a lotion or tonic or shampoo containing trigonelline, but also several other chemical species including vitamin B6, nicotinic acid or acid amide, and d-Ca pantothenate (column 3, lines 52 to 54, and following disclosures; claims 12 and 13).

It is not clear from the disclosures in US '958 which chemical species in their lotions or shampoos provides the desired effects, particularly since the mechanism of action of compositions applied to the skin or hair would be expected to be different from orally administered compositions.

Furthermore, US '958 does <u>not</u> disclose or suggest the effectiveness of trigonelline in repairing, restructuring or strengthening hair.

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Repairing, restructuring or strengthening hair is different from conventional hair care as explained on page 3, last five lines of text, to page 4, lines 1 to 8, of the written description in applicants' specification. Conventional hair care involves improving combability and/or luster of the hair and/or hair styling and/or increasing hair volume and thus is different from restructuring, repairing or strengthening hair.

Thus applicants' method as claimed in claims 32 and 40 is a new method of using the known trigonelline and/or its salts for repairing, restructuring or strengthening hair. The effectiveness of trigonelline for these latter purposes is not disclosed or suggested in US '958.

The chemical method of the applicants helps the hair to resist treatments that tend to damage the hair, such as bleaching or permanent shaping of the hair. There is no suggestion in US '958 that the treatment with trigonelline and/or its salts will help to improve the resistance of the hair to damaging cosmetic treatments, such as oxidative dyeing, bleaching or permanent shaping.

Furthermore applicants' comparative experimental results on pages 8 to 14 of the specification have clearly established the effectiveness of their claimed method in improving abrasion resistance and also improving tear strength of the hair. No such comparative results are presented in the prior art of record.

Furthermore independent claims 32 and 40 claim a method of treatment with critical acting time and temperature range limitations with subsequent rinsing. US '958 does not teach or suggest either the acting time range or

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temperature range limitations of the independent claims. US '958 does not teach the step of rinsing after the critical acting time range. Rinsing can be used because the increase in hair strength or abrasion resistance does not require that agent composition to remain on the hair, but is only due to the action of the agent during the critical acting time range.

In addition, in contrast to the statements on page 3 of the Office Action US '958 does <u>not</u> disclose or suggest the salts of trigonelline (compounds of formula (II)) or in the case of the dependent claims the applicants' preferred active ingredients according to new dependent claims 39 and 41.

US '077 discloses and claims a method of protecting keratinous fibers, such as hair, from damage by applying at least one plant extract to the fibers. The paragraph bridging columns 4 and 5 of US '077 discloses that <u>any</u> plant extract protects the keratinous fibers from damage, which is noted in the Office Action. US '077 is cited for teaching the conditions of leaving the extract on the hair at room temperature for a certain acting time and then rinsing according to the first paragraph on page 4 of the Office Action (see example 3 in column 8 of Cannell).

However the action of any protective substance depends on its chemical composition so that the conditions of acting time and temperature used in a protective method and whether or not rinsing can occur depend on the chemical

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composition of the treatment agent. There is no relationship between the chemical composition of the treatment agent of example 3 of US '077 and the applicants' claimed composition, because US '077 does not disclose a composition containing any trigonelline and/or salts of formulas (I) and (II).

In fact, US '077 does not mention trigonelline and/or salts of formulas (I) and (II) for any purpose at all in their treatment compositions! The similar compounds such as carnitine and betaine are not mentioned as active ingredients for protecting hair. Thus since the applicants' ingredients are not included the conditions of the method of US '077, such as acting times and temperature ranges, cannot be expected to be helpful to one skilled in the art to determine or even suggest the corresponding temperature ranges for a method of treating hair with e.g. the shampoos or lotions of US '958.

Of course if one coats the hair with a substance that forms a barrier coating, the diffusion of species, such as a protein, or the like would reasonably be at least reduced and thus the hair would be protected. In this sense the compositions of US '077 protect hair against damage.

However US '077 like US '958 does not teach or suggest that their compositions can be used to treat hair in order to improve the tear resistance of the hairs or to improve the abrasion resistance of the hair, as claimed in new claim 40. Similarly US '077 does not disclose or suggest methods of

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strengthening, restructuring or repairing hair.

Claim 32 has been amended so that it no longer claims protecting the hair in general by application of the agent containing the trigonelline and/or the salts of formula (II). Claim 40 also does not claim this sort of general protective method, but instead focuses on specific properties of the hair that are improved with the result that the resistance of the hair to damaging treatments, such as bleaching or permanent shaping, is improved.

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C. Rationale for Obviousness

Applicants respectfully disagree with the rationale in the last paragraph on page 4 of the Office Action. Merely because US '958 teaches lotions and shampoos comprising trigonelline, but also several other chemical species including vitamin B6, nicotinic acid or acid amide, and d-Ca pantothenate, does not suggest or teach that they leave the hair stronger with greater tear resistance or abrasion resistance, when they are rinsed from the hair. US '958 does not teach anything regarding methods of improving tear resistance or abrasion resistance.

The compositions of US '077 do protect the hair but comprise any plant extract. US '077 does not mention compositions containing trigonelline and/or the compounds of formulas (II) according to applicants' claims 32 and 40. Thus US '077 cannot teach or suggest anything regarding the method step features of the

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method claimed in applicants' claims, because the treatment compositions of US DEC 2 1 2010 '958 and US '077 are entirely different.

Neither US '958 nor US '077 suggest that trigonelline or their salts of formula (II) are effective in repairing, restructuring, or strengthening hair in the case of claim 32 and in increasing tear and abrasion resistance in the case of claim 40.

For the aforesaid reasons and because of the changes in method claim 32, withdrawal of the rejection of claims 32 to 36 and 38 as obvious under 35 U.S.C. 103 (a) over U.S. Patent 5,133,958 (US '958) and U.S. Patent 6,861,077 (US '077) is respectfully requested.

Furthermore because the aforesaid reasons it is respectfully submitted that new claims 39 to 41 should not be rejected as obvious under 35 U.S.C. 103 (a) over U.S. Patent 5,133,958 (US '958) and U.S. Patent 6,861,077 (US '077).

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

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In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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